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Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: FUSION PROTEINS OF MYCOBACTERIUM TUBERCULOSIS ANTIGENS AND THEIR USES

(57) Abstract

The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

1. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

2. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

3. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

4. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

5. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

6. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

7. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

8. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

9. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

10. The present invention relates to fusion proteins containing at least two *Mycobacterium tuberculosis* antigens. In particular, it relates to bi-fusion proteins which contain two individual *M. tuberculosis* antigens, tri-fusion proteins which contain three *M. tuberculosis* antigens, tetra-fusion proteins which contain four *M. tuberculosis* antigens, and penta-fusion proteins which contain five *M. tuberculosis* antigens, and methods for their use in the diagnosis, treatment and prevention of tuberculosis infection.

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INTERNATIONAL SEARCH REPORT

International Application No.

PCT/US 99/07717

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 C12N15/31 C07K14/35 C07K19/00 C12P21/02 A61K39/04

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 C07K C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 97 09428 A (CORIXA CORP) 13 March 1997 (1997-03-13) abstract example 3 page 138 -page 139 claims	1-13
X	WO 97 09429 A (CORIXA CORP) 13 March 1997 (1997-03-13) abstract example 3 page 150 -page 152 claims	1-13



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

25 November 1999

Date of mailing of the international search report

14/12/1999

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INTERNATIONAL SEARCH REPORT

Inter application No

PCT/US 99/07717

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>PHILIPP W.J.: "An integrated map of the genome of th tubercle bacillus, Mycobacterium tuberculosis H37Rv, and comparison with Mycobacterium leprae" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, vol. 93, 1996, pages 3132-3137, XP002121036 WASHINGTON US abstract column 1, paragraph 1</p>	1-13
A	<p>WO 95 01441 A (STATENS SERUMSINSTITUT ;ANDERSEN PETER (DK); ANDERSEN AASE BENGGAAR) 12 January 1995 (1995-01-12) abstract disclosure, examples</p>	2-8, 10-13
X	<p>LEE B.-Y. ET AL.: "Characterization of the major membrane protein of virulent Mycobacterium tuberculosis" INFECTION AND IMMUNITY., vol. 60, 1992, pages 2066-2074, XP002086104 AMERICAN SOCIETY FOR MICROBIOLOGY. WASHINGTON., US ISSN: 0019-9567 the whole document</p>	2-8, 10-13
A	<p>WO 95 01440 A (STATENS SERUMINSTITUT ;HASLOEV KAARE (DK); ANDERSEN AASE BENGGAARD) 12 January 1995 (1995-01-12) abstract disclosure, examples</p>	1-13
A	<p>US 5 330 754 A (MUNSHI ANIL ET AL) 19 July 1994 (1994-07-19) column 5, line 1 -column 8, line 25 examples 1,2 claims</p>	1-13

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 99/ 07717

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 9-11
because they relate to subject matter not required to be searched by this Authority, namely:
Remark: Although claims 9-11
are directed to a method of treatment of the human/animal
body, the search has been carried out and based on the alleged
effects of the compound/composition.
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such
an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all
searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment
of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report
covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is
restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/07717

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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